

117TH CONGRESS  
2D SESSION

# H. R. 6875

To update the National Action Plan for Adverse Drug Event Prevention to provide educational information on adverse drug events and pharmacogenomic testing, to improve electronic health records for pharmacogenomic information, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 28, 2022

Mr. SWALWELL (for himself and Mr. EMMER) introduced the following bill; which was referred to the Committee on Energy and Commerce

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## A BILL

To update the National Action Plan for Adverse Drug Event Prevention to provide educational information on adverse drug events and pharmacogenomic testing, to improve electronic health records for pharmacogenomic information, and for other purposes.

1       *Be it enacted by the Senate and House of Representa-  
2 tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4       This Act may be cited as the “Right Drug Dose Now  
5 Act”.

6 **SEC. 2. TABLE OF CONTENTS.**

7       The table of contents of this Act is as follows:

Sec. 1. Short title.  
Sec. 2. Table of contents.  
Sec. 3. National Action Plan for Adverse Drug Event Prevention.  
Sec. 4. Adverse drug event and pharmacogenomic testing awareness.  
Sec. 5. Improving EHR systems to improve the use of pharmacogenomic information.  
Sec. 6. Increased authorization for pharmacogenomics implementation research.  
Sec. 7. Definition.

**1 SEC. 3. NATIONAL ACTION PLAN FOR ADVERSE DRUG  
2 EVENT PREVENTION.**

3 The Secretary of Health and Human Services shall—  
4 (1) not later than 180 days after the date of  
5 enactment of this Act, in coordination with the  
6 heads of other relevant Federal departments and  
7 agencies including the Director of the National  
8 Human Genome Research Institute, and in consulta-  
9 tion with the Director of the Eunice Kennedy Shriv-  
10 er National Institute of Child Health and Human  
11 Development, the Director of the National Center  
12 for Biotechnology Information, and the Director of  
13 the National Library of Medicine, submit a report to  
14 the Congress on—

15 (A) the implementation of the National Ac-  
16 tion Plan for Adverse Drug Event Prevention of  
17 the Department of Health and Human Services;  
18 and  
19 (B) the progress in meeting the target ap-  
20 proved by the Federal Interagency Steering

Committee for Adverse Drug Events for a 10-percent reduction for—

(i) the rate of adverse drug events in anticoagulants among United States patient stays;

(ii) the rate of adverse drug events from hypoglycemic agents among United States inpatient stays;

(iii) the rate of adverse drug events from opioid analgesics among United States inpatient stays;

(iv) the rate of visits to United States hospital emergency departments for adverse drug events associated with injury from oral anticoagulants;

(v) the rate of visits to United States hospital emergency departments for adverse drug events associated with injury from insulin; and

(vi) the rate of visits to United States hospital emergency departments for adverse drug events associated with therapeutic use of opioid analgesics;

(2) convene the Federal Interagency Steering Committee for Adverse Drug Events to update the

1       National Action Plan for Adverse Drug Event Pre-  
2       vention; and

3               (3) require such Committee, in updating the  
4       National Action Plan for Adverse Drug Event Pre-  
5       vention—

6                       (A) to consider advances in scientific un-  
7       derstanding and technology pertaining to drug-  
8       gene-drug interactions, clinical outcomes, health  
9       care utilization, and the decreasing cost of ge-  
10      netic testing;

11                      (B) to assess the role of pharmacogenetics  
12      testing combined with clinical decision support  
13      as an evidence-based prevention tool; and

14                      (C) to evaluate operating characteristics  
15      for Federal adverse drug event surveillance sys-  
16      tems and expand capabilities to identify genetic  
17      associations in adverse events.

18 **SEC. 4. ADVERSE DRUG EVENT AND PHARMACOGENOMIC**  
19 **TESTING AWARENESS.**

20       Part P of title III of the Public Health Service Act  
21      (42 U.S.C. 280g et seq.) is amended by adding at the end  
22      the following:

23      **“SEC. 399V-7. ADVERSE DRUG EVENT AND**  
24      **PHARMACOGENOMIC TESTING AWARENESS.**

25      “(a) PUBLIC EDUCATION CAMPAIGN.—

1                 “(1) IN GENERAL.—The Secretary, acting  
2 through the Director of the National Human Ge-  
3 nome Research Institute, in consultation with the  
4 Director of the Eunice Kennedy Shriver National In-  
5 stitute of Child Health and Human Development,  
6 the Director of the National Center for Bio-  
7 technology Information, and the Director of the Na-  
8 tional Library of Medicine, shall conduct a national  
9 evidence-based education campaign to increase the  
10 public’s awareness regarding—

11                 “(A) the prevalence of adverse drug events  
12 and adverse drug reactions;

13                 “(B) specific risk factors that increase an  
14 individual’s likelihood of experiencing an ad-  
15 verse drug event or adverse drug reaction;

16                 “(C) basic information about  
17 pharmacogenomic testing and how its use, in-  
18 cluding incorporation in comprehensive medica-  
19 tion management, may prevent adverse drug re-  
20 actions in certain clinical situations;

21                 “(D) the role of health care providers in  
22 performing pharmacogenomic testing, inter-  
23 preting the results of such testing, and adjust-  
24 ing medications based on such results;

1                         “(E) the availability of pharmacogenomic  
2                         testing;

3                         “(F) comprehensive medication manage-  
4                         ment; and

5                         “(G) how the benefits of an individual’s  
6                         pharmacogenomic test results might change or  
7                         be relevant over time.

8                 “(2) CONSIDERATION OF ADVICE OF STAKE-  
9                         HOLDER EXPERTS.—The education campaign under  
10                  paragraph (1) shall take into consideration the ad-  
11                  vice of stakeholder experts, such as those special-  
12                  izing in medical genetics and pharmacogenetics and  
13                  collaborative communities focused on  
14                  pharmacogenomics.

15                 “(3) MEDIA CAMPAIGN.—In conducting the  
16                  education campaign under paragraph (1), the Sec-  
17                  retary, after considering the advice of stakeholder  
18                  experts pursuant to paragraph (2), may award  
19                  grants or contracts to entities to establish national  
20                  multimedia campaigns that may include advertising  
21                  through television, radio, print media, billboards,  
22                  posters, all forms of existing and especially emerging  
23                  social networking media, other Internet media, and  
24                  any other medium determined appropriate by the  
25                  Secretary.

1               “(4) RURAL REGIONS, HEALTH PROFESSIONAL  
2               SHORTAGE AREAS, AND UNDERSERVED COMMU-  
3               NITIES.—The Secretary shall ensure that the edu-  
4               cation campaign under paragraph (1)—

5               “(A) reaches rural and medically under-  
6               served communities (as defined in section 799);  
7               and

8               “(B) includes the involvement of commu-  
9               nity health centers, community pharmacies, and  
10               other local health clinics.

11               “(b) HEALTH CARE PROFESSIONAL EDUCATION  
12               CAMPAIGN.—

13               “(1) IN GENERAL.—The Secretary, acting  
14               through the Director of the National Human Ge-  
15               nome Research Institute, in consultation with the  
16               Director of the Eunice Kennedy Shriver National In-  
17               stitute of Child Health and Human Development,  
18               the Director of the National Center for Bio-  
19               technology Information, the Director of the National  
20               Library of Medicine, and the Administrator of the  
21               Health Resources and Services Administration, shall  
22               establish a national health education program for  
23               health care providers and health care leaders, includ-  
24               ing administrators, pharmacists, nurse practitioners,  
25               physicians' assistants, physician medical geneticists,

1 laboratory medical geneticists, genetic counselors,  
2 medical educators, and the faculty of schools of med-  
3 icine and other schools of health professions, on the  
4 following:

5 “(A) Pharmacogenomic testing and the ex-  
6 tent of its ability to prevent adverse drug reac-  
7 tions.

8 “(B) Pharmacogenomic testing, drug inter-  
9 action alerting systems, when to refer to or con-  
10 sult with a genetics provider, and the standards  
11 of care for patients who are suspected or known  
12 to have a genetic variant that is known to im-  
13 pact drug metabolism.

14 “(C) Evidence-based information that  
15 would encourage individuals and their health  
16 care professionals to consider pharmacogenomic  
17 testing as part of their health care plan to the  
18 extent appropriate.

19 “(D) The role of medical professionals who  
20 specialize in genetics and genomics.

21 “(E) How to incorporate  
22 pharmacogenomics into comprehensive medica-  
23 tion management.

24 “(2) GRANTS.—

1                 “(A) AWARD.—In carrying out the na-  
2                 tional health education program under this sub-  
3                 section, the Secretary, acting through the Di-  
4                 rector of the National Human Genome Re-  
5                 search Institute, may award grants to nonprofit  
6                 organizations to carry out educational activities  
7                 with respect to the topics listed in subpara-  
8                 graphs (A) through (D) of paragraph (1).

9                 “(B) USE OF FUNDS.—A grant under sub-  
10                 paragraph (A) may be used to support one or  
11                 more of the following activities:

12                 “(i) Increasing the knowledge and  
13                 awareness of health care providers and  
14                 health care leaders about  
15                 pharmacogenomic testing and drug inter-  
16                 actions.

17                 “(ii) Increasing the number of health  
18                 professional schools that incorporate  
19                 pharmacogenomic curricula in classroom  
20                 instruction.

21                 “(iii) Increasing the ability of health  
22                 care providers to note and respond to the  
23                 impact of gender, ethnicity, age, and other  
24                 relevant characteristics on drug metabo-  
25                 lism.

1                     “(iv) Developing principles, practices,  
2                     and curriculum instruction that prepare  
3                     medical, nursing, pharmacy, and other  
4                     health professions students to effectively  
5                     apply knowledge and skills needed to rec-  
6                     ognize—

7                     “(I) when a patient is eligible for  
8                     pharmacogenomic testing, including  
9                     as part of comprehensive medication  
10                    management when appropriate, and in  
11                    accordance with the patient’s health  
12                    care team, a drug product’s label, and  
13                    professional clinical guidelines; and

14                    “(II) how to appropriately use  
15                    the test results to adjust a prescrip-  
16                    tion or otherwise change a patient’s  
17                    health care plan.

18                    “(v) Providing opportunities for prac-  
19                    ticing health care professionals to receive  
20                    pharmacogenomics training and education  
21                    through a variety of modalities including  
22                    in-person, electronic media, professional  
23                    meetings and conferences, and social  
24                    media.

1       “(c) REPORTING.—At least every three years, the  
2 Secretary, acting through the Director of the National  
3 Human Genome Research Institute, in consultation with  
4 the Director of the Eunice Kennedy Shriver National In-  
5 stitute of Child Health and Human Development, the Di-  
6 rector of the National Center for Biotechnology Informa-  
7 tion, the Director of the National Library of Medicine, the  
8 Administrator of the Centers for Medicare & Medicaid  
9 Services, and relevant stakeholders with expertise in devel-  
10 oping quality measures of label and peer-reviewed profes-  
11 sional guidelines on drug-gene interactions, shall publish  
12 data on—

13           “(1) the public’s awareness regarding adverse  
14 drug events and pharmacogenomic testing;

15           “(2) the number or percentage of individuals  
16 utilizing information to inform their health care de-  
17 cisions regarding prescription medications and  
18 pharmacogenomic testing;

19           “(3) the change in the number or percentage of  
20 individuals enrolled in a prescription drug plan  
21 under part D of the title XVIII of the Social Secu-  
22 rity Act receiving a pharmacogenetic test, as rec-  
23 ommended in alignment with a drug product’s label  
24 or peer-reviewed professional guidelines; and

1               “(4) the number or percentage of changes, be-  
2       ginning one year after the date of enactment of this  
3       section, in medication management as a result of in-  
4       corporating information from pharmacogenomic test-  
5       ing.

6       “(d) DEFINITIONS.—In this section:

7               “(1) ADVERSE DRUG EVENT.—The term ‘ad-  
8       verse drug event’ means an injury resulting from  
9       any medical intervention with a drug.

10              “(2) ADVERSE DRUG REACTION.—The term  
11       ‘adverse drug reaction’ means a response to a drug  
12       that—

13              “(A) is noxious and unintended; and

14              “(B) occurs at doses normally used in hu-  
15       mans for prophylaxis, diagnosis, or therapy of  
16       disease or for the modification of physiologic  
17       function.

18              “(e) AUTHORIZATION OF APPROPRIATIONS.—To  
19       carry out this section, there is authorized to be appro-  
20       priated \$50,000,000 for each of fiscal years 2022 through  
21       2027.”.

22 **SEC. 5. IMPROVING EHR SYSTEMS TO IMPROVE THE USE**  
23 **OF PHARMACOGENOMIC INFORMATION.**

24       (a) CERTIFICATION CRITERIA.—The Secretary of  
25       Health and Human Services (in this section referred to

1 as the “Secretary”) shall adopt pursuant to subtitle A of  
2 title XXX of the Public Health Service Act (42 U.S.C.  
3 300jj–11 et seq.) certification criteria for health informa-  
4 tion technology, including for electronic prescribing sys-  
5 tems and real-time pharmacy benefit checks, such that be-  
6 fore a medication order is completed and acted upon dur-  
7 ing computerized provider order entry, interventions must  
8 automatically indicate to a user—

9                 (1) when pharmacogenomic testing is appro-  
10                 priate based on a drug product’s label or peer-re-  
11                 viewed professional guidelines; and

12                 (2) drug-gene and drug-drug-gene associations,  
13                 established by a drug product’s label or peer-re-  
14                 viewed professional guidelines, based on a patient’s  
15                 medication list, medication allergy list, and results  
16                 from pharmacogenomic testing.

17                 (b) REPORTING AND ASSOCIATION OF ADVERSE  
18 DRUG EVENTS.—The Secretary, in consultation with the  
19 Commissioner of Food and Drugs, shall carry out a pro-  
20 gram to improve the reporting of adverse drug events and  
21 the association, if any, of such events to a patient’s genetic  
22 status. As part of the program, the Secretary shall issue  
23 regulations pursuant to the Federal Food, Drug, and Cos-  
24 metic Act (21 U.S.C. 301 et seq.) and other applicable  
25 statutory authorities to—

1                   (1) ensure that drug-gene interaction alerting  
2       systems are continuously updated to incorporate in-  
3       formation from new or updated drug labels with  
4       pharmacogenomic information and newly established  
5       peer-reviewed professional guidelines on drug-gene  
6       associations;

7                   (2) facilitate the reporting of adverse drug  
8       events to the FDA Adverse Event Reporting System  
9       directly through the use of the health care provider's  
10      electronic health record system; and

11                  (3) allow for the reporting of whether an ad-  
12       verse drug event is caused by pharmacogenetic inter-  
13       actions to the FDA Adverse Event Reporting Sys-  
14       tem directly through the use of the health care pro-  
15       vider's electronic health record system.

16                  (c) UPDATING FAERS; PATIENT-FRIENDLY RE-  
17       PORTING.—The Secretary, acting through the Commis-  
18       sioner of Food and Drugs, shall—

19                  (1) update the FDA Adverse Event Reporting  
20       System, including to—

21                          (A) accept information directly from health  
22       care providers' electronic health record systems;

23                          (B) improve the collection of real world  
24       evidence (as defined in section 505F of the

1           Federal Food, Drug, and Cosmetic Act (21  
2           U.S.C. 355g)); and

3                 (C) create a selection tool that allows individuals to report whether an adverse drug event  
4                 is associated with a drug-gene interaction;

5                 (2) work with relevant Federal agencies and offices, and stakeholders, to create patient-friendly  
6                 electronic options for reporting adverse drug events  
7                 such as submission through a designated mobile de-  
8                 vice application or mobile device messaging applica-  
9                 tion; and

10                 (3) not later than 1 year after the date of en-  
11                 actment of this Act, report to the Congress on the  
12                 progress made in implementing paragraphs (1) and  
13                 (2).

14                 (d) ASSESSMENT ON ADDITIONAL IMPROVEMENTS  
15                 TO ELECTRONIC HEALTH RECORD SYSTEMS.—

16                 (1) IN GENERAL.—Not later than 180 days  
17                 after the date of enactment of this Act, the Sec-  
18                 retary shall—

19                 (A) complete an assessment on additional  
20                 improvements to electronic health record sys-  
21                 tems that are needed to further the develop-  
22                 ment of real world evidence (as defined in sec-  
23                 tion 505F of the Federal Food, Drug, and Cos-

1               metic     Act     (21     U.S.C.     355g))     in  
2               pharmacogenomics; and

3               (B) submit a report to the Congress on the  
4               findings on the assessment.

5               (2) CONSIDERATION OF NEEDED ADVANCE-  
6       MENTS.—As part of the assessment under para-  
7       graph (1), the Secretary shall consider what ad-  
8       vancements are needed to capture information about  
9       the laboratory and the test used as part of  
10      pharmacogenomic testing.

11 **SEC. 6. INCREASED AUTHORIZATION FOR**  
12               **PHARMACOGENOMICS IMPLEMENTATION RE-**  
13               **SEARCH.**

14       There is authorized to be appropriated to the Na-  
15 tional Institutes of Health \$7,000,000 for each of fiscal  
16 years 2022 through 2025 for the conduct, support, and  
17 maintenance of pharmacogenomics implementation re-  
18 search through the Genomic Community Resources pro-  
19 gram.

20 **SEC. 7. DEFINITIONS.**

21       In this Act:

22               (1) The term “adverse drug event” means an  
23       injury resulting from any medical intervention with  
24       a drug.

1                   (2) The term “comprehensive medication man-  
2                   agement” means medication management pursuant  
3                   to a standard of care that ensures each patient’s  
4                   medications are individually assessed to determine  
5                   that each medication is appropriate for the patient,  
6                   effective for the medical condition, and safe given  
7                   the comorbidities and other medications being taken  
8                   and able to be taken by the patient as intended.

